Applicant: Feng-Nien Ko et al. Attorney's Docket No.: 11544-003001 / 0641-5101US

Serial No.: 09/522,434 Filed: March 9, 2000

Page : 8 of 9

REMARKS

Initially, Applicants would like to thank the Examiner for granting the telephone interview on December 9, 2003, regarding this application. At the Examiner's suggestion, Applicants hereby file this second request for continued examination.

In the Office Action dated May 6, 2003, the Examiner rejected claim 1 and its dependent claim 11 for being anticipated by U.S Patent No. 4,317,816 ("'816 patent"), JP 04316507A ("JP '507"), and JP 61109732A ("JP '732"). The claims are drawn to a composition containing an American ginseng extract. In the response to the Office Action, Applicants pointed out that the extract recited in claim 1 contains (1) ether-soluble components, which are not present in the extract taught in the '816 patent, and (2) compounds having molecular weights of between 1,000 and 10,000, which are not present in the extract taught in JP '507 or JP '732.

Nonetheless, in the Final Office Action dated October 31, 2003, the Examiner maintained her rejection, contending that (1) the phrase "ether-soluble components" was not recited in claims at issue, and (2) the "ginseng extract" recited in claim 1 covered prior art extracts for reciting the phrase "at least 1,000."

During the above-mentioned interview, Applicants' counsel pointed out that the American ginseng extract recited in claim 1 inherently contains (1) ether-soluble components and (2) compounds having molecular weights of between 1,000 and 10,000 dalton, and therefore differs from those taught in the cited references. Applicants requested that the corresponding limitations be entered into the claim. The Examiner agreed to enter the "molecular weight" limitation but not the "ether-soluble components" limitation, contending that the preparation steps recited in claim 1 did not inherently produce an American ginseng extract containing ether-soluble components even though the transition phrase "American ginseng extract consisting essentially of" was recited. A letter summarizing the interview was sent to the Examiner on December 10, 2003. Applicants have attached hereto a copy of this letter as "Exhibit A."

For the purpose of moving this case toward allowance, Applicants have filed herewith a second request for continued examination and amended claim 1 to point out that the process recited in claim 1 is essentially closed ended. See the recitation "a process consists essentially of." In other words, it does not include other steps, e.g., ether precipitation taught in the '816

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Serial No.: 09/522,434 Filed : March 9, 2000

Page

: 9 of 9

patent. Accordingly, the American ginseng extract recited in claim 1 inherently contains ethersoluble components and therefore differs from that in the '816 patent.

The extract also inherently contains compounds having molecular weights of between 1,000 and 10,000 dalton. See Yoshikawa et al. (Chem. Pharm. Bull. 46(4): 647-654, 1998), which was presented with Applicants' response filed on December 11, 2002.

Upon entry of the amendments, claims 1, 3-5, 7-9, and 11-37 are pending. Claims 1, 3, 11, and 23-37 are under examination. In view of the above amendments and remarks, as well as the remarks provided in the last response, Applicants submit that amended claim 1 is not anticipated by the '816 patent, JP '507, or JP '732. Claims 11 and 23-37 all depend from amended claim 1 directly or indirectly. They are therefore also not anticipated by the cited art.

CONCLUSION

Applicants submit that the grounds for the rejection asserted by the Examiner have been overcome, and that claims, as pending, define subject matter that is novel. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.

Applicants ask that all claims be allowed. This response is being filed concurrently with a Request for Continued Examination with the required fee of \$385.00. Please apply any other charges to Deposit Account No. 06-1050, referencing Attorney Docket No. 11544-003001.

Respectfully submitted,

2-2-02 Date:

Jianming Hao Reg. No. 54,694

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W.K. Richardson 1859-1951

December 10, 2003

Examiner Susan D. Coe U.S. Patent & Trademark Office Commissioner for Patents Washington, D.C. 20231

Re: Anti-Ulcer Pharmaceutical Composition And The Preparation Thereof

Applicant:

Feng-Nien Ko et al.

Application No.:

09/522,434

Filing Date:

March 9, 2000

Our Ref.:

11544-003001

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TWIN CITIES

WASHINGTON, DC

Dear Examiner Coe:

We thank you for spending time with us to discuss the final office action in a telephone interview yesterday. This is a follow-up to our discussion.

During the telephone interview, we pointed out that the American ginseng extract recited in claim 1 inherently contains (1) ether-soluble components and (2) compounds having molecular weights of between 1,000 and 10,000 dalton, and therefore differs from those taught in the references you relied on. We asked you to enter the corresponding limitations into the claim. You agreed to enter the "molecular weight" limitation but not the "ether-soluble components" limitation. You contended that the preparation steps recited in claim 1 does not inherently produce an American ginseng extract containing ether-soluble components even though the transition phrase "consisting essentially of" is recited.

For the purpose for moving this case toward allowance, we propose amending claim 1 as follows:

- (Currently amended) A pharmaceutical composition for preventing or treating peptic ulcer, comprising:
- an American ginseng extract in an amount effective for preventing or (i) treating peptic ulcer; and
 - a pharmaceutically acceptable carrier;

wherein said American ginseng extract consists essentially of a preparation obtained by a process consisting essentially of extraction with a solvent, centrifugation, and filtration through an ultrafiltration membrane-with molecular weight cut off at least 1,000 to give a retentate, and concentration of the retentate, and the retentate contains compounds having molecular weights of between 1,000 and 10,000 dalton.

FISH & RICHARDSON P.G.

Examiner Susan D. Coe December 10, 2003 Page 2

Note that the preparation process consists essentially of only three steps, excluding other steps, e.g., ether precipitation. Accordingly, the American ginseng extract recited in claim 1 inherently contains ether-soluble components.

The extract also inherently contains compounds having molecular weights of between 1,000 and 10,000 dalton. See Yoshikawa et al. (Chem. Pharm. Bull. 46(4): 647-654, 1998), which was presented with our response filed on December 11, 2002.

Incidentally, we are attaching two letters, one to you and the other to our client, that summarize two previous telephone interviews. During the second interview, you agreed that independent claim 1 would be allowed if we recited the phrase "consisting essentially of" and suggested filing a request continued examination. We followed your suggestion.

We thank you again for your attention to this matter and will call you in a day or two after you have considered the proposed amendments to claim 1.

Very truly yours,

Y. Rocky Tsao, Ph.D., J.D.

Reg. No. 34,053